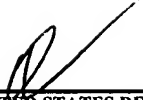




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,471	06/25/2003	Abram Katz	13425-115001 / BV-1025 US	3516
26161	7590	08/29/2007	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			WOOD, AMANDA P	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			08/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/606,471	Applicant(s) KATZ ET AL.	
	Examiner Amanda P. Wood	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 7 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, 18-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 June 2007 has been entered.

Claims 1, 4, 7, and 18-26 are presented for consideration on the merits.

Applicant's arguments with respect to claims 1, 4, 7, and 18-26 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 19, 22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, Applicant recites the phrase "contacting a candidate agent with a SMCE-regulating factor" in line 3 of claim 4 and the phrase "determining whether the candidate agent increases glucose uptake in a mammalian cell" in lines 6-7. The limitation of "determining whether the candidate agent increases glucose uptake in a mammalian cell" lacks antecedent basis with

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respect to the rest of claim 4, because the candidate agent is contacted with a SMCE-regulating factor, not with the mammalian cell. It is unclear from the current phrasing of the claim how the increase in glucose uptake in a mammalian cell is linked with contacting a candidate agent with a SMCE-regulating factor (i.e., does the mammalian cell comprise a SMCE-regulating factor or something else?).

Furthermore, it is unclear what Applicant intends to encompass by "SMCE-regulating factor" in claim 4 (is this factor a cell, a protein, a peptide fragment, etc.?).

Claims 19, 22, and 25 depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, and 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Westfall et al (Am. J. Physiol. 1990).

A method is claimed of identifying an agent that increases glucose uptake in a mammalian cell, contacting the mammalian cell with a candidate agent, determining whether the candidate agent increases store-mediated calcium-entry (SMCE) into the

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cell, and determining whether the candidate agent increases glucose uptake into the cell, wherein the glucose uptake is insulin-stimulated glucose uptake.

Westfall et al teach a method wherein rat soleus muscles (i.e., mammalian skeletal muscles) were isolated and contacted with either  $\text{Ca}^{2+}$  agonists or antagonists which modify cellular calcium to determine their effect on calcium uptake as well as their effect on glucose uptake in the muscle cells. Westfall et al determined the level of insulin-mediated glucose uptake in the muscle cells for each agonist or antagonist and confirmed whether the effects on sugar transport resulted from agonistic actions on  $\text{Ca}^{2+}$  channels. In particular, Westfall et al teach that when the  $\text{Ca}^{2+}$  agonist BAY K 8644 was added to muscle cells, insulin-mediated glucose transport was enhanced. Westfall et al also teaches that the  $\text{Ca}^{2+}$  antagonists Nifedipine and diltiazem block the glucose uptake changes caused by BAY K 8644, and that nifedipine also attenuated the  $\text{Ca}^{2+}$  uptake caused by BAY K 8644 (see, for example, pg. R466). Furthermore, Westfall et al teach that the effect of increased insulin-mediated glucose transport seen with the  $\text{Ca}^{2+}$  agonist is mediated through modulation of cellular  $\text{Ca}^{2+}$  levels, since these effects were blunted by the antagonists (see, for example, Abstract).

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 7, and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westfall et al.

Westfall et al is relied upon for the reasons set forth above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of identifying compounds that modulate glucose transport in mammalian cells disclosed by Westfall et al, based upon the beneficial teachings provided therein, with respect to the teachings that compounds which increase  $\text{Ca}^{2+}$  uptake in muscle cells have an agonistic effect on insulin-mediated glucose uptake in muscle cells, as discussed above. Therefore, based upon these beneficial teachings, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Westfall et al so as to identify agents which increase insulin-mediated glucose uptake in mammalian cells for the express purpose of providing compounds to treat conditions related to impaired insulin-mediated glucose uptake, such as diabetes type 2.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

**Conclusion**

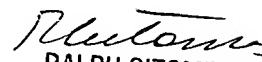
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW  
Examiner  
Art Unit 1657

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

APW